K092168

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

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NOV 1 6 2009

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Date Prepared: July 16, 2009

Device Name

Proprietary name: Elecsys HCG+β CalCheck 5
Common name: HCG+β CalCheck 5
Classification name: Single (specified) analyte controls (assayed and unassayed)

Predicate device

The Elecsys HCG+β CalCheck 5 is substantially equivalent to other products in commercial distribution intended for similar use. We claim equivalency to the currently marketed Elecsys HCG+β CalCheck (K010237).

Device Description

The Elecsys HCG+β CalCheck 5 is a lyophilized product consisting of HCG in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys HCG+ β CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the reportable range established by the Elecsys HCG+β reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

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Comparison Table

The table below compares Elecsys HCG+β CalCheck 5 with the predicate device, Elecsys HCG+β Calcheck (K010237).

Characteristic	Elecsys HCG+β CalCheck (K010237)	Elecsys HCG+β CalCheck 5
Intended Use	For use in the verification of the calibration established by the Elecsys HCG+β reagent on Elecsys 1010 or 2010 immunoassay analyzers.	The Elecsys HCG+ β CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the reportable range established by the Elecsys HCG+β reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.
Levels	Three	Five
Format	Lyophilized	Same
Handling	Reconstitute Check 1 and Check 2 with exactly 1.0 mL distilled or deionized water. Reconstitute Check 3 with exactly 1.5 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.	Reconstitute Check 1, Check 2, Check 3, Check 4, and Check 5 with exactly 1.0 mL distilled or deionized water. Allow to stand closed for 15 minutes, then mix gently by inversion.
Stability	Unopened: Store at 2-8°C until expiration date Reconstituted: 20 – 25°C : 4 hrs	Same
Matrix	Human serum matrix	Same

Performance Characteristics

The Elecsys HCG+β CalCheck 5 was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Roche Diagnostics
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NOV 1 6 2009

Re: k092168
Trade/Device Name: Elecsys hCG+β CalCheck 5
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: October 20, 2009
Received: October 21, 2009

Dear Ms. Baumann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092168

Device Name: Elecsys HCG+β CalCheck 5

Indication For Use:

The Elecsys HCG+β CalCheck 5 is an assayed control for use in calibration verification and for use in the verification of the assay range established by the Elecsys HCG+β reagent on the indicated Elecsys and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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